



UNITED STATES PATENT AND TRADEMARK OFFICE

cm
UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/538,716	06/10/2005	Toshiya Fujisato	AKA-0286	6913
23599 7590 06/01/2007 MILLEN, WHITE, ZELANO & BRANIGAN, P.C. 2200 CLARENDON BLVD. SUITE 1400 ARLINGTON, VA 22201			EXAMINER MAKAR, KIMBERLY A	
			ART UNIT 1636	PAPER NUMBER
			MAIL DATE 06/01/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/538,716	Applicant(s) FUJISATO ET AL.	
	Examiner Kimberly A. Makar, Ph.D.	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 30 April 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2 and 4-11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2 and 4-11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Arguments

1. Currently, claims 2, 4-11 are pending. Cancellation of claims 1 and 3 by applicant in the amendment dated 4/30/07 are acknowledged.
2. Any rejection not maintained in this office action is withdrawn. Applicant's arguments, see response, filed 4/30/07, with respect to the rejection(s) of claim(s) 1-10 under 102(b) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. These arguments are directed toward the fact that Anderson does not teach immersing the tissue in a treating solution and irradiating the tissue. However, upon further consideration, a new ground(s) of rejection is made in view of Giberson et al (US Patent 6,875,583) in view of Anderson et al (US 5,571,216) (see below).
3. In light of the new rejection, the finality of the Office Action mailed 1/29/07 is withdrawn.

Specification

4. A substitute specification for the claims is required pursuant to 37 CFR 1.125(a) because the specification is not is proper idiomatic English.
5. A substitute specification must not contain new matter. The substitute specification must be submitted with markings showing all the changes relative to the immediate prior version of the specification of record. The text of any added subject

Art Unit: 1636

matter must be shown by underlining the added text. The text of any deleted matter must be shown by strike-through except that double brackets placed before and after the deleted characters may be used to show deletion of five or fewer consecutive characters. The text of any deleted subject matter must be shown by being placed within double brackets if strike-through cannot be easily perceived. An accompanying clean version (without markings) and a statement that the substitute specification contains no new matter must also be supplied. Numbering the paragraphs of the specification of record is not considered a change that must be shown.

6. Examples of improper English and grammatical errors are disclosed below, through the first half of the specification:

In the heart valve replacement, for example, xenogeneic heart valves are prepared from porcine heart valves or bovine pericardia by treating with glutaraldehyde to diminish their immunogenicity. (Page 1)

Moreover, cases in which functional failure appeared at relatively early stage have been reported among young recipients suggesting the involvement of immune reactions. In Ross operation know to be effective in young recipients, autologous pulmonary valve is transplanted to aortic valve site and the impaired pulmonary valve is reconstructed with cryopreserved allogeneic valve. (page 2)

Harverich et al. of Hannover University, School Medicine, Germany published a decellularization method using a detergent Triton X-100 and proteolytic enzyme trypsin solutions. (page 3)

As evidenced from BSE and CJD infections in the dura transplantation, safety assurance is very important for the tissue to be transplanted. (page 4)

7. It is, therefore, an object of this invention to provide a method which can eliminate or ameliorate the disadvantages of prior art, namely the method can accomplish, first, removal of cellular components, bacteria and viruses from large size tissues, second, treatment without impairing the biomechanical properties of the tissue, and, thirdly, sterilization of the tissue in a simple manner in a short period of time. (pages 4-5)

Art Unit: 1636

8. According to the present invention, there is provided a method of treating native tissues of mammalian origin comprising immersing said tissue a treating solution, and irradiating said tissue with microwave while maintaining the temperature thereof at a temperature in the range between 0°C and 40°C. (page 5)

9. Fig. 3 is a graph showing the efficiency of removal of Triton X-100 from decellularized porcine heart valve. (page 6)

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

11. Claims 2, and 4-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

12. Claim 10 and dependent claims 2, 4-9, and 11 recite "a method of decellularization." The term "decellularization" is not defined in the specification. Is "decellularization" the removal of a certain amount of cells? Is it the loss of a single cell? A skilled artisan would be unable to determine the metes and bounds of the claimed invention.

13. Claim 10 and dependent claims 2, 4-9, and 11 recite, "a method of decellularizing native tissue of mammalian origin comprising immersing said tissue in a treating solution, and irradiation the immersed tissue with microwaves while maintaining the temperature of the tissue in the range between 0°C and 40°C, whereby said tissue is decellularized." It is unclear if the method reads: 1) immersing the tissue in a treating

Art Unit: 1636

solution, and *then* irradiating the tissue with microwaves (thus the method comprises two steps, where in the second step the tissue is not required to be immersed in a treating solution) or 2) immersing the tissue in a treating solution, and while still immersed (or concurrently), irradiating the immersed tissue with microwaves. A skilled artisan would be unable to determine the metes and bounds of the claimed invention because it is unclear which of these alternative interpretations of the claims is intended.

For the purposes of prosecution the following is defined:

14. The specification teaches a treating solution is a detergent solution, a hypotonic solution, a hypertonic solution, or fixing reagents, such as glutaraldehyde (page 8 of the instant specification).

15. There is no teaching for a definition of decellularization. It is being defined as “the loss of at least a cell” from a tissue being treated according to the broadest reasonable interpretation of the claim limitation.

16. Claim 10 recites, “a method of decellularizing native tissue of mammalian origin comprising immersing said tissue in a treating solution, and irradiation the immersed tissue with microwaves while maintaining the temperature of the tissue in the range between 0°C and 40°C, whereby said tissue is decellularized.” Using the broadest reasonable interpretation, this claim can be interpreted two ways: 1) immersing the

Art Unit: 1636

tissue in a treating solution, and *then* irradiating the tissue with microwaves or 2) immersing the tissue in a treating solution, and while still immersed (or concurrently), irradiating the immersed tissue with microwaves. For the purposes of prosecution, the method is being read as, immersing the tissue in a treating solution, and while still immersed (or concurrently), irradiating the immersed tissue with microwaves.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

17. Claims 2, 5, 7-8, and 10-11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giberson et al (US Patent Publication US20020177183) in view of Anderson et al (US 5,571,216). Claims 2, 5, 7-8, and 10-11 recite a method of

Art Unit: 1636

decellularizing native tissue of mammalian origin comprising immersing said tissue in a treating solution, and irradiating the tissue with microwaves while maintaining the temperature of the tissue in the range between 0°C and 40°C, whereby said tissue is decellularized (claim 10). The method is further limited wherein said treatment is decellularization of said tissue, and wherein said treating solution is water, a hypertonic solution, a hypotonic solution, a detergent, and enzyme or a liquid medium (claim 2), and where said tissue is soft tissue (claim 5) or an organ or part thereof (claim 7). The method is further limited comprising a step of washing said tissue with a fresh washing liquid following irradiation (claim 8). The method is further limited wherein said tissue is immersed in said treating solution received in a microwave-transmitting container which is in turn in heat exchange contact with a coolant liquid received in a microwave-transmitting vessel, and wherein said tissue is irradiated with microwaves in a microwave oven while circulating said coolant liquid through an external cooling apparatus (claim 11).

18. The preamble of the claims, "a method of decellularizing native tissue" bears no patentable weight, as this appears to be the result the microwaving immersed tissue in any treating solution while maintaining the temperature within a wide range. A preamble is generally not given any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness, but instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 197 F.2d 150, 152, 88 USPQ 578, 481

(CCPA 1951). Absent evidence to the contrary, any method which performs the same steps of microwaving immersed tissue in any treating solution while maintaining the temperature within the same range teaches the same method.

19. Giberson et al teaches a method of microwave-assisted fixation of tissue (see abstract). Giberson teaches that the tissue is suspended in a liquid medium of formalin or aldehyde solutions (see abstract), where the tissue is fully immersed in the medium (see claims 1 and 5), that the tissue, while suspended in formalin solution is irradiated in a microwave oven, while controlling the fluid temperature in the range of 4°C to 40°C, where a cooling effect of the fluid prevents the microwave irradiation from heating the specimen beyond 4°C to 40°C (see claim 6). While these claims are directed to two irradiation times, Giberson teaches that it can be done in a one step microwave oven process (see abstract).

20. Giberson teaches that the tissue is placed in a plastic microwave vessel (standard plastic microwave processing cassette), which is placed in a recirculation device placed in the microwave oven and previously filled with a fixative solution. The fixative is pumped from inside the microwave oven through the recirculation device which is external to the microwave oven in order to cool the tissue (see figure 2A and 2B). The entire device set-up is depicted in figures 1A-1D. The circulating fluid would result in the loss of some cells prior to complete fixation, thus resulting in decellularization of the suspended tissue.

21. Absent evidence to the contrary, and in light of the specification wherein the treating solution comprises fixing reagents, Giberson teaches a method of

Art Unit: 1636

decellularization tissue comprising immersing said tissue in a liquid medium treating solution, and irradiating the immersed tissue with microwaves from a microwave oven while maintaining the temperature of the tissue in the range between 0 and 40°C by an external cooling apparatus which circulates the cooling liquid. Giberson teaches his method overcomes known problems in the art regarding the use of microwaves on fresh tissue preparations where fixatives are heated in a microwave faster than they are able to penetrate the tissue, thus resulting in the poor fixation of samples (column 2, line 45 through column 3, line 13). Giberson teaches his method is usable on all tissues, including mineralized (ie hard tissue) and non-mineralized tissue (column 4, lines 58-59). Giberson does not teach that the method is performed on mammalian tissue, the types of tissues, or washing the tissues.

22. Anderson et al (US Patent No. 5,571,216) teaches a method of tissue welding comprising immersing the tissue in a welding bath (treating solution) and heating the tissue at a temperature of 40°C (column 8, lines 28- 37). Anderson specifically teaches mammalian tissue welding on bovine and porcine tissue (column 8, lines 28-43) as well as rabbit tendons and skin (column 9, lines 26-28). Anderson teaches that the welding bath comprises water (column 5, line 30) and that the method further comprises a chemical fixation step comprising a solution that contains glutaraldehyde (column 7, lines 18-29). Anderson teaches that welding of cut surface tissues occurs by clamping the tissue together wherein needles are inserted into and through the two tissues, where the needles are supplied with a heated fluid. The hot liquid is collected at the

Art Unit: 1636

other end of the needles by a similar block with holes for receiving each of the needle tips (column 5, lines 25-40).

23. Anderson's Examples section teaches:

Fresh bovine Achilles tendon and fresh porcine skin were cut into 2 mm thick transverse discs, which were placed between sealed microscope coverslips clamped together and immersed in a circulating water bath at different temperatures for different times. Other samples were welded in a moist atmosphere by heating between two stainless steel temperature controlled plates instrumented with pressure and distance gauges, with equivalent results...After removal from the welding bath, some of the discs were quenched by immersion in a second bath at different temperatures, as low as 0oC, and then assayed for tensile strength (column 8, lines 28-43).

24. Thus Anderson teaches that the welding with clamps occurs with the tissue immersed in a circulating water bath, and *then* assayed for tensile strength. He teaches different specific examples of heating in the example, "moist atmosphere" and "water bath" etc, and further teaches that heating can occur via microwaves (see column 3, lines 10-20).

25. Anderson teaches that more complicated heating devices can be utilized, including microwave ovens (column 6, lines 1-2). Anderson teaches heating the tissue for a period of 1 hour (column 8, lines 37-39). Anderson teaches that the native tissue to be treated includes vascular vessels as well as parts of whole organs including the gut (column 1, lines 42-45). Finally, Anderson teaches that the method of treatment further comprises a washing step following heating with ice cold physiological saline after the weld is complete (column 8, lines 16-24 and 40-41).

26. A skilled artisan would have been motivated to combine the teaching of Giberson on a method of fixing tissues immersed in a fixation solution using a microwave, while maintaining a constant temperature, which Giberson teaches is usable on all tissue

types further with the teaching of Anderson on a method of tissue welding and fixation on mammalian tissue which Anderson teaches his welding method is malleable and utilizes different methods specifically to test which heating method produces the strongest weld, and suggests the use of microwave irradiation because the use of Giberson's method would have provided one more heating method already shown to have positive and reliable fixation effects on fresh tissue samples, thereby improving Anderson's method. It would have been obvious to combine the teaching of Giberson on a method of fixing tissue sections with microwaves wherein the tissue is immersed in a coolant comprising a fixative solution further with the teaching of Anderson on a method of tissue welding and tissue fixation comprising heating tissue sections using a multiple ways to heat the welding solution because Giberson teaches his method results in a faster, more efficient method of fixing tissue and Anderson teaches his method of tissue welding and fixation is malleable and even tests different modes of heating the tissue including the use of microwaves, thus it would have been obvious to improve the method of Anderson and utilize the microwave oven and cooling apparatus of Giberson in order to further reduce the time and improve the efficiency of Anderson's welding method. Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the instant invention was made, it must be considered that said ordinary skilled artisan would have had reasonable expectation of success in practicing the claimed invention.

27. Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Giberson et al (US Patent 6,875,583) and Anderson et al (US Patent No. 5,571,216) as applied to

Art Unit: 1636

claim 10 above, and further in view of Kearns et al (US Patent No. 4,963,708). Claim 4 states a method of treating a native tissue of mammalian origin comprising immersing the tissue in a treating solution, and irradiating the immersed tissue with a microwave while maintaining the temperature of the tissue in the range between 0°C and 40°C wherein the tissue is irradiated with microwave at a frequency of 2450 MHz for a net period of time from 1 hour to 1 week.

28. Giberson et al (US Patent Publication US20020177183) and Anderson et al (US Patent No. 5,571,216) teach a method of tissue fixation and welding comprising immersing the tissue in a fixation solution and heating the immersed tissue using a microwave at a temperature of 4 to 40°C by pumping the fixation solution through a cooling apparatus which is outside of the microwave oven for 1 hour (see above). Giberson teaches the microwave is used at 450 W and 250 W, but it can range from 50W to 900 W depending on the tissue (column 5, lines 62-64 and column 6, lines 41-46). Giberson and Anderson teach heating the tissue for a period of 1 hour (column 5, lines 62-64 and column 8, lines 37-39, respectively) however neither Giberson nor Anderson teach using a microwave at 2450 MHz.

29. Kearns et al (US Patent No. 4,963,708) teaches a method and apparatus for cooking utilizing a microwave and a double-boiler apparatus. Specifically, Kearns et al teaches that, "essentially all domestic microwave ovens operate at 2450 MHz" (Column 1, lines 23-24).

30. The skilled artisan would have been motivated to combine the teachings of Giberson and Anderson on the method of native mammalian tissue-fixation and welding

Art Unit: 1636

comprising the immersion of tissue in a treating solution and heating the immersed tissue in a microwave to a temperature of 4-40°C for one hour with the teaching of Kearns that all domestic microwave ovens operate at the frequency of 2450 MHz because doing so would not require a special (*ie* more expensive or hard to find) microwave oven in order to perform the method. It would have been obvious to the skilled artisan to combine the teaching of Giberson and Anderson on the method of native mammalian tissue-fixation and welding comprising the immersion of tissue in a treating solution and heating the solution in a microwave to a temperature of 40°C for one hour with the teaching of Kearns that all domestic microwave ovens operate at the frequency of 2450 MHz because using the specific frequency that most microwave ovens already use would allow for easily obtainable and readily available equipment for the artisan utilizing the method of treating native tissue. Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the instant invention was made, it must be considered that said ordinary skilled artisan would have had reasonable expectation of success in practicing the claimed invention.

31. Claims 6 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Giberson et al (US Patent 6,875,583) and Anderson et al (US Patent No. 5,571,216) as applied to claim 10 above, and further in view of Boyce et al (US Patent No. 6,123,731) of record 7/28/06. Claim 6 states a method of treating a native tissue of mammalian origin comprising immersing the tissue in a treating solution, and irradiating the immersed tissue with a microwave while maintaining the temperature of the tissue in the range between 0°C and 40°C wherein the native tissue to be treated is hard tissue

Art Unit: 1636

including bone, cartilage, and teeth (claim 6) and wherein the native tissue to be treated has been pretreated to facilitate the removal of donor cells (claim 9).

32. Giberson et al (US Patent Publication US20020177183) and Anderson et al (US Patent No. 5,571,216) teach a method of tissue fixation and welding comprising

immersing the tissue in a fixation solution and heating the immersed tissue using a microwave at a temperature of 4 to 40°C by pumping the fixation solution through a cooling apparatus which is outside of the microwave oven for 1 hour (see above).

Anderson specifically teaches mammalian tissue welding on bovine and porcine tissue (column 8, lines 28-43) as well as rabbit tendons and skin (column 9, lines 26-28).

Giberson teaches his method is usable on all tissues, including mineralized (ie hard tissue) and non-mineralized tissue (column 4, lines 58-59). Neither Giberson nor

Anderson teach the native tissue to be treated includes bone, cartilage, or teeth nor that the native tissue is to be pretreated to facilitate the removal of donor cells.

33. Boyce et al (US Patent No. 6,123,731) teaches a method of tissue welding comprising immersing human bone fragments (see examples 4 and 5) as well as bovine and porcine bones (column 4, lines 1-5) into a treating solution, and heating the tissue using a microwave (column 6, lines 33-43 and column 7 lines 34-36 and claim 28).

Boyce also teaches that the bone fragments are demineralized prior to heat treatment by bathing the bone in a 0.6 HCL bath (See examples 1-5).

34. The skilled artisan would have been motivated to combine the teachings of Giberson and Anderson on the method of native mammalian tissue-fixation and welding comprising the immersion of tissue in a treating solution and heating the solution in a

Art Unit: 1636

microwave to a temperature of 40°C for one hour with the teaching of Boyce et al on the method of tissue welding comprising bone and the pretreatment of the bone to remove all donor cells because Giberson teaches his method is appropriate for all tissues including mineralized (hard tissue) tissue and Boyce's teaching broadens the type of hard tissue that the method is capable of treating thereby increasing the applicability for treating multiple tissue types allowing for the treatment of more patients with more transplants and implants all utilizing the same treatment method. Furthermore, the pretreatment of the tissue to remove donor cells would reduce the likelihood for the generation of an immune response in the patient, but also exposes the collagen fibers allowing for crosslinking between bone sheets (Boyce claims 1-4). It would have been obvious to the skilled artisan to combine the teaching of Giberson and Anderson on the method of native mammalian tissue-fixation and welding comprising the immersion of tissue in a treating solution and heating the solution in a microwave to a temperature of 40°C for one hour with the teaching of Boyce on the method of tissue welding comprising bone because the scope of the treatment becomes broader, allowing for the treatment of additional diseases and patients with the same methodology. Additionally, the pretreatment of the tissue to remove donor cells would reduce the likelihood for the generation of an immune response in the patient, but also exposes the collagen fibers allowing for crosslinking between bone sheets (claims 1-4). Given the teachings of the prior art and the level of skill of the ordinary skilled artisan at the time the instant invention was made, it must be considered that said ordinary skilled artisan would have had reasonable expectation of success in practicing the claimed invention.

Conclusion


35. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kimberly A. Makar, Ph.D. whose telephone number is 571-272-4139. The examiner can normally be reached on 8AM - 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach, Ph.D. can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Kam/05/16/07


Daniel M. Sullivan
Primary Examiner